

AMENDMENTS TO THE CLAIMS

1-14. (Cancelled)

15. (Previously presented) A method for verifying the efficiency of sample preparation of test sample nucleic acids and the performance of nucleic acid amplification and detection practiced on a test sample after its preparation, said method comprising:

(i) providing a universal internal control reagent comprising a bacterial spore, said internal control reagent having at least one internal control (IC) nucleic acid target sequence therein, wherein said internal control reagent is an internal control for the release, amplification, and detection of a nucleic acid from said test sample;

(ii) mixing said internal control reagent and said test sample;

(iii) submitting said test sample mixed with said internal control reagent to a sample preparation procedure in order to release both said nucleic acid from said test sample and said IC nucleic acid target sequence from said internal control reagent; and

(iv) submitting a product from said sample preparation procedure to amplification and detection for the amplification and detection of both said IC nucleic acid target sequence and said nucleic acid of the test sample, wherein detection of said IC nucleic acid target sequence is indicative of both efficient sample preparation and performance of nucleic acid amplification.

16. (Previously presented) The method as defined in claim 15, further comprising

(v) comparing the amplification and detection performed in (iv) to the amplification and detection performed with a control reaction to evaluate the efficiency of the sample preparation and the performance of the nucleic acid amplification and detection practiced on said test sample and reagent.

17. (Previously presented) The method of claim 15, wherein said sample preparation procedure comprises concentrating and/or purifying cells, spores, or cells comprising organelles and/or viral particles prior to lysis.

18-20. (Cancelled)

21. (Currently amended) The method of claim ~~20~~15, wherein said spore is a *Bacillus* spore.

22. (Previously presented) The method of claim 21, wherein said spore is a *Bacillus globigii* spore.

23. (Previously presented) The method of claim 15, wherein said IC nucleic acid target sequence is on a cloning vector.

24. (Previously presented) The method of claim 15, wherein said IC nucleic acid target sequence is on a plasmid vector.

25. (Previously presented) The method of claim 15, wherein said nucleic acid amplification method is PCR.

26. (Previously presented) The method of claim 15, wherein said IC nucleic acid target sequence is nucleic acid sequence of clinical, environmental, alimentary or human origin.

27. (Previously presented) The method of claim 15, wherein said IC nucleic acid target sequence is a nucleic acid sequence of microbial origin.

28. (Previously presented) The method of claim 15, wherein the said test sample is a sample of clinical, environmental or alimentary origin.

29. (Previously presented) The method of claim 15, wherein said test sample comprises a vaginal/anal or a nasal swab.

30. (Previously presented) The method of claim 15, wherein said sample preparation procedure comprises

(i) concentration and/or purification of cells, spores or cells comprising organelles and/or viral particles,

(ii) lysis of cells, spores, or cells comprising organelles and/or viral particles,

(iii) nucleic acid extraction,

(iv) elimination, neutralization and/or inactivation of nucleic acid testing (NAT) inhibitors, and/or

(v) nucleic acid concentration and/or purification.

31. (Cancelled)

32. (Previously presented) A method for verifying the efficiency of sample preparation of test sample nucleic acids and the performance of nucleic acid amplification and detection practiced on a test sample after its preparation, said method comprising:

(i) providing a universal internal control reagent comprising a bacterial spore, said internal control reagent having at least one internal control (IC) nucleic acid target sequence therein, wherein said internal control reagent is an internal control for the release, amplification and detection of a nucleic acid from said test sample;

(ii) mixing said internal control reagent and said test sample;

(iii) submitting said test sample with said mixed internal control reagent to a nucleic acid amplification procedure in order to release both said nucleic acid from said test sample and said IC nucleic acid target sequence from said internal control reagent; and

(iv) submitting a product from said amplification procedure to further amplification or detection for the amplification or detection of both said IC nucleic acid target sequence and said nucleic acid of the test sample, wherein detection of said IC nucleic acid target sequence is indicative of both efficient sample preparation and performance of nucleic acid amplification.

33. (Previously presented) The method of claim 32, wherein said sample preparation procedure comprises concentrating and/or purifying cells, spores, or cells comprising organelles and/or viral particles prior to lysis.

34-36. (Cancelled)

37. (Currently amended) The method of claim ~~36~~32, wherein said spore is a *Bacillus* spore.

38. (Previously presented) The method of claim 37, wherein said spore is a *Bacillus globigii* spore.

39. (Previously presented) The method of claim 32, wherein said IC nucleic acid target sequence is on a cloning vector.

40. (Previously presented) The method of claim 32, wherein said IC nucleic acid target sequence is on a plasmid vector.

41. (Previously presented) The method of claim 32, wherein said nucleic acid amplification method is PCR.

42. (Previously presented) The method of claim 32, wherein said IC nucleic acid target sequence is nucleic acid sequence of clinical, environmental, alimentary or human origin.

43. (Previously presented) The method of claim 32, wherein said IC nucleic acid target sequence is a nucleic acid sequence of microbial origin.

44. (Previously presented) The method of claim 32 wherein the said test sample is a sample of clinical, environmental or alimentary origin.

45. (Previously presented) The method of claim 32, wherein said test sample comprises a vaginal/anal or a nasal swab.

46. (Previously presented) The method of claim 32, wherein said sample preparation method comprises

- (i) concentration and/or purification of cells, spores, or cells comprising organelles and/or viral particles,

- (ii) lysis of cells, organelles or cells comprising organelles and/or viral particles,

- (iii) nucleic acid extraction,

- (iv) elimination, neutralization and/or inactivation of nucleic acid testing (NAT) inhibitors, and/or

- (v) nucleic acid concentration and/or purification.

47. (Previously presented) The method of claim 15, wherein said amplification reaction comprises contacting said product from said sample preparation procedure with a primer pair comprising SEQ ID NO:7 and SEQ ID NO:8.

48. (Previously presented) The method of claim 32, wherein said amplification reaction comprises contacting said product from said sample preparation procedure with a primer pair comprising SEQ ID NO:7 and SEQ ID NO:8.

49. (Previously presented) The method of claim 15, wherein said spore is purified prior to mixing with said test sample.

50. (Previously presented) The method of claim 32, wherein said spore is purified prior to mixing with said test sample.

51. (Previously presented) The method of claim 49, wherein said purification eliminates vegetative cells from said internal control reagent.

52. (Previously presented) The method of claim 40, wherein said purification eliminates vegetative cells from said internal control reagent.

53. (Previously presented) The method of claim 15, wherein said internal control reagent comprises about 500 spores.

54. (Previously presented) The method of claim 32, wherein said internal control reagent comprises about 500 spores.

55. (Previously presented) The method of claim 15, wherein said amplification reaction comprises contacting said product from said sample preparation procedure with a first primer pair designed to amplify said internal control nucleic acid target, and a second primer pair designed to amplify said nucleic acid from said test sample, wherein the first and second primer pairs are different.

56. (Previously presented) The method of claim 32, wherein said amplification reaction comprises contacting said product from said sample preparation procedure with a first primer pair designed to amplify said internal control nucleic acid target, and a second primer pair designed to amplify said nucleic acid from said test sample, wherein the first and second primer pairs are different.

57. (Currently amended) The method of claim ~~53~~55, wherein the amplification product of said second primer pair is shorter than the amplification product of said first primer pair.

58. (Currently amended) The method of claim ~~54~~56, wherein the amplification product of said second primer pair is shorter than the amplification product of said first primer pair.